

## **REMARKS**

This paper is filed in response to the Office Action dated January 31, 2008. Claims 1, 2, 4, 6-8, 10-17, 19, 25-31, 54, 55, 57-62, 64, 65, 68-71, 73-77, 79-84, and 86-89 are pending in the Application. Claims 1, 2, 4, 6-8, 10-17, 19, 25-31, 61, 62, 64, 65, 68-71, 73-77, and 79 are allowed. Claims 54-55, 57-60, 80-84, and 86-89 stand rejected by the Office Action. By this paper, claims 54, 57, 80, and 81 are amended.

### **Allowable Subject Matter**

The Applicants thank the Examiner for allowing claims 1, 2, 4, 6-8, 10-17, 19, 25-31, 61, 62, 64, 65, 68-71, 73-77, and 79. These claims remain as previously filed and thus remain in condition for allowance.

### **Claim Objections**

Claims 54 and 57 were objected to for referencing a container, rather than a pre-filled container. Claims 54 and 57 have been amended to replace all references to a container with references to a pre-filled container. The Applicants therefore respectfully request that the objection to claims 54 and 57 be withdrawn.

### **Claim Rejections – 35 U.S.C. § 103**

Claims 54-55, 57-60, 80-84, and 86-89 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,637,087 issued to O'Neil et al.

("O'Neil") in view of U.S. Patent No. 5,795,336 issued to Romano et al. ("Romano"). The Applicants respectfully traverse these rejections. However, in order to expedite prosecution of the Application, independent claims 54 and 80 have been amended.

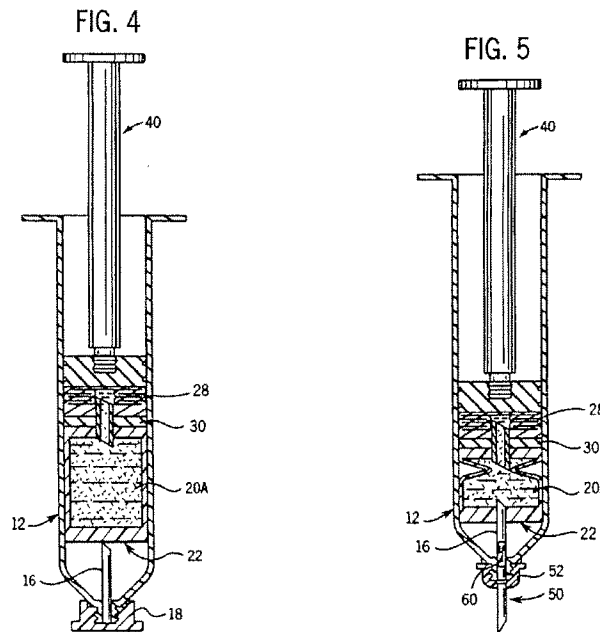
Claim 54

Independent claim 54 has been amended to recite, *inter alia*,  
  
an empty chamber in the housing configured to receive medicinal fluid from the pre-filled container and to deliver medicinal fluid to the injection needle, wherein the chamber is configured to receive substantially all of the medicinal fluid from the pre-filled container prior to establishment of fluid communication between the chamber and the injection needle.

O'Neil and Romano both fail to disclose at least the foregoing limitations of claim 54, and thus claim 54 is not obvious in view of these references.

For example, the Office Action identifies the cannula 16 of O'Neil as an empty chamber for receiving medicinal fluid from a container. However, the cannula 16 of O'Neil is connected to a needle 50 to thereby establish fluid communication between the cannula 16 and the needle 50 before liquid is introduced into the cannula 16 from a container 22. See O'Neil, column 5, lines 31-35 and 51-60; Figs. 4 and 5 (reproduced below). Nowhere does O'Neil disclose introducing liquid into the cannula 16 from the container 22 and then placing the cannula 16 in fluid communication with the needle 50. Moreover, to introduce liquid into the cannula 16 in this manner would be counterintuitive due to extra care that would be required to

prevent liquid within the cannula 16 from spilling as the cannula 16 is connected to the needle 50.



The Office Action cites Romano for the proposition that the retractable needle disclosed in this reference could be combined with the pre-filled syringe system of O'Neil. However, Romano clearly lacks any disclosure of a chamber configured to receive medicinal fluid from a pre-filled container prior to establishment of fluid communication between the chamber and an injection needle. Therefore, the Applicants respectfully submit that amended claim 54 is not obvious in view of O'Neil and Romano, and thus request that the rejection of this claim under 35 U.S.C. § 103(a) be withdrawn.

#### Claims 55 and 57-60

Each of claims 55 and 57-60 depends from claim 54, either directly or indirectly, and thus includes all of the limitations of claim 54. Therefore, for at least

the reasons discussed above with respect to claim 54, O'Neil and Romano fail to render claims 55 and 57-60 obvious. The Applicants thus respectfully request that the rejection of claims 55 and 57-60 under 35 U.S.C. § 103(a) be withdrawn.

#### Claim 80

Independent claim 80 has been amended to recite, *inter alia*, "a seal operable to retain fluid within the chamber when closed and to permit medicinal fluid to be expelled from the chamber through the needle when opened." O'Neil and Romano both fail to disclose at least the foregoing limitations of claim 80, and thus claim 80 is not obvious in view of these references.

For example, the Office Action identifies the pierceable surfaces of the containers 22, 28 of O'Neil as a seal, and further identifies the cannula 16 as a chamber. However, none of the surfaces of the containers 22, 28 is operable to retain fluid within the cannula 16 when the surfaces are closed. Rather, these surfaces, when closed, isolate the cannula 16 from the contents of the containers 22, 28. Only when the cannula 16 pierces a surface of the container 22 is fluid introduced into the cannula 16, and once it is pierced, this surface does not retain fluid within the cannula 16. See O'Neil, Fig. 5 (reproduced above).

The Office Action cites Romano for the proposition that the retractable needle disclosed in this reference could be combined with the pre-filled syringe system of O'Neil. However, Romano clearly lacks any disclosure of a seal operable to retain fluid within a chamber when closed and to permit medicinal fluid to be expelled from the chamber through a needle when opened. Therefore, the Applicants respectfully

submit that amended claim 80 is not obvious in view of O'Neil and Romano, and thus request that the rejection of this claim under 35 U.S.C. § 103(a) be withdrawn.

Claims 81-84 and 86-89

Each of claims 81-84 and 86-89 depends from claim 80 and thus includes all of the limitations of this claim. Therefore, for at least the reasons discussed above with respect to claim 80, O'Neil and Romano fail to render claims 81-84 and 86-89 obvious. The Applicants thus respectfully request that the rejection of claims 81-84 and 86-89 under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

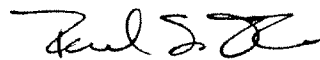
In view of the foregoing remarks, the Applicants submit that each of the pending claims is in condition for allowance. Should questions exist after consideration of the foregoing, the Patent Office is kindly requested to contact Applicants' attorney at the telephone number given herein.

Please continue sending all correspondence to the following address:

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Respectfully submitted,



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